510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k042329

B. Purpose for Submission:
Addition of new assay matrix (plasma)

C. Analyte:
Salicylate

D. Type of Test:
Quantitative colorimetric assay

E. Applicant:
Diagnostic Chemicals Limited

F. Proprietary and Established Names:
Salicylate-SL Assay

G. Regulatory Information:

1. Regulation section:
   21 CFR§862.3830
2. Classification:
   Class II
3. Product Code:
   DKJ
4. Panel:
   Toxicology (91)

H. Intended Use:

1. Intended use(s):
   See below.

2. Indication(s) for use:
   "The Diagnostic Chemicals Limited's Salicylate method is an in vitro diagnostic device intended to measure salicylate levels in human serum or plasma (lithium heparin). Such measurements are used in the diagnosis of salicylate toxicity and overdose."

3. Special condition for use statement(s):
   This assay is for prescription use only

4. Special instrument Requirements:
   The assay is intended to be used on automated chemistry analyzers or generic spectrophotometers.

I. Device Description:

This device contains three liquid ready-to-use components; a component that contains a buffer solution containing salicylate hydroxylase, stabilizers, and a preservative, a component that contains buffer with NADH, and a salicylate standard.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Salicylate-SL Assay
2. Predicate K number(s):
   k981872
3. Comparison with predicate:
   The two devices are identical except this submission adds plasma as an additional sample matrix.

K. Standard/Guidance Document Referenced (if applicable):

This submission did not reference any performance standard documentation but did reference FDA guidance documents on submission preparation.

L. Test Principle:

Salicylate hydroxylase catalyzes the conversion of salicylate and NADH to catechol and NAD in the presence of oxygen. The resulting decrease in absorbance (due to the conversion of NADH to NAD) is directly proportional to the concentration of salicylate in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. ***Precision/Reproducibility:***
      Within run precision was determined from 20 replicates of two levels ('low' and 'high') of spiked plasma run in a single assay. Run-to-run precision was determined by triplicate measurements of two level of spiked plasma in five separate assays. The results are presented below:

Precision of Salicylate-SL Assay (Plasma mg/dL)

Plasma Level	Criteria	Within Run	Run-to-Run
Low	**Mean**	20.48	22.76
	Std. Dev	0.50	1.02
	CV	2.4 %	4.5 %
	n=	20	15
High	**Mean**	46.20	52.75
	Std. Dev	1.09	1.56
	CV	2.4 %	3.0 %
	n=	20	15

These results met the manufacturer's specification of a coefficient of variation of <5%.

b. Linearity/assay reportable range:

A salicylate-spiked plasma sample was diluted with saline to cover the linear range. Quadruplicate samples at 11 levels (0 to 130 mg/dL) were measured on a Hitachi 717 analyzer. The calculated regression equation is y=0.999x – 0.769, r=0.988.

Linearity of Salicylate-SL Assay (Plasma, mg/dL)

Assigned Value	Mean	% Recovery
0	0.315*	---
2.72	1.54*	56.6
3.88	3.26	84.1
5.43	4.46	82.0
16.17	15.96	98.7
21.60	2042	94.5
26.91	26.86	99.8
53.94	51.47	95.4
80.85	78.47	97.1
107.76	107.57	99.8
129.36	129.36	100

***** Below lower limit of detection (see below).

These results support the manufacture's claim of linearity between 3 – 100 mg/dL. Linearity of serum was established in the predicate submission.

c. Traceability, Stability, Expected values (controls, calibrators, or method):

These parameters were addressed in the predicate submission.

d. Detection limit:

Ten samples of saline were analyzed and the lower limit of detection was calculated from the mean plus three standard deviations. This value, 3.3 mg/dL, was in excellent agreement with the value in the predicate submission, 3 mg/dL.

e. Analytical specificity:
Analytical specificity was established in serum in the predicate version of this assay. It is not expected that plasma samples would perform differently.

f. Assay cut-off:
Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:
Serum and plasma samples were drawn from twenty-five people and salicylate levels were tested with the assay on an Advia 1650 analyzer. The following regression statistics were calculated from this data.

Method Comparison, Salicylate Assay: Serum versus Plasma

Slope	0.993
Intercept	0.665
R value	0.9998
N	25
Range	0 – 155 mg/dL

Performance of serum samples in this assay was compared to a similar salicylate method in the predicate, yielding equivalent performance.

b. Matrix comparison:
Direct comparison of serum and plasma recoveries from the same sample is illustrated in the table below. Pooled donor blood was spiked with different levels of salicylate then serum and plasma fractions were separated and analyzed in triplicate and averaged; acceptable variance was set at <10%.

Comparison of Serum and Plasma Recovery: Salicylate Assay

Sample	Serum Recovery (mg/dL)	Plasma Recovery (mg/dL)	% Variance between serum and plasma
Level 1	57.6	54.0	6.3%
Level 2	68.6	70.8	3.2%
Level 3	92.3	93.3	1.1%

3. Clinical studies:

a. Clinical sensitivity:
Not applicable to this type of device.

b. Clinical specificity:
Not applicable to this type of device.

c. Other clinical supportive data (when a and b are not applicable):
Not applicable to this type of device.

4. Clinical cut-off:
   Not applicable to this type of device.

5. Expected values/Reference range:
   Kaplan and Szabo state that the toxic concentration of salicylate is 30 mg/dL (2.17 mmol).

N. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.